DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-678

Bristol-Myers Squibb Company
Attention: Amy Jennings, Ph.D.
5 Research Parkway, Dept. 718
Signature 91 Building
Wallingford, CT 06492

Dear Dr. Jennings:

Please refer to your new drug application dated October 27, 2003, received October 28, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tequin® (gatifloxacin) for Oral Suspension.

We acknowledge receipt of your submissions dated:

November 4, 2003	November 11, 2003	December 11, 2003
December 16, 2003	January 8, 2004	January 15, 2004
January 20, 2004	January 29, 2004 (2)	February 3, 2004 (2)
February 4, 2004 (2)	February 5, 2004 (2)	February 9, 2004
February 13, 2004 (2)	February 23, 2004	February 24, 2004
March 1, 2004 (2)	March 2, 2004 (2)	March 16, 2004
March 30, 2004	March 31, 2004 (2)	April 5, 2004
April 13, 2004 (3)	April 16, 2004 (2)	April 19, 2004
April 20, 2004 (2)	April 27, 2004 (2)	April 29, 2004 (3)
April 30, 2004 (2)	May 5, 2004 (2)	May 26, 2004 (2)
May 27, 2004 (2)	June 8, 2004 (2)	July 20, 2004 (2)
July 21, 2004 (2)	August 4, 2004 (2)	August 16, 2004
August 23, 2004	August 25, 2004	

This new drug application provides for a new dosage form, Tequin® (gatifloxacin) for Oral Suspension.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert submitted on August 25, 2004; immediate carton and container labels submitted on August 23, 2004). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). These guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that the labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. For administrative purposes, this submission should be designated **"FPL for approved NDA 21-678."** Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, significant modifications of existing indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. For this application, we are waiving the pediatric study requirement for ages 0 months to 18 years for acute sinusitis, uncomplicated urinary tract infections, uncomplicated skin and skin structure infections, and acute exacerbations of chronic bronchitis; and we are deferring pediatric studies for ages 0 months to 18 years for community acquired pneumonia and complicated urinary tract infections (including pyelonephritis). We are also deferring pediatric studies for uncomplicated gonorrhea in post-pubertal males and females.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The statuses of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for the treatment of community acquired pneumonia in pediatric patients ages 0 months to 18 years.

   Final Report Submission: August 27, 2009

2. Deferred pediatric study under PREA for the treatment of complicated urinary tract infections, including pyelonephritis, in pediatric patients ages 0 months to 18 years.

   Final Report Submission: August 27, 2009

3. Deferred pediatric study under PREA for the treatment of uncomplicated gonorrhea in post-pubertal males and females.

   Final Report Submission: August 27, 2009

Please submit final study reports to this NDA. For administrative purposes, all submissions related to these pediatric postmarketing study commitments must be clearly designated "**Required Pediatric Study Commitments.**"

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. Please submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified."

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you should have any questions, please call Anne Marie Homonnay-Weikel, Pharm D, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure (labeling)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Renata Albrecht

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